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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,254	12/06/2000	Augusto Inventi Solari	P101615 -0000	8796

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EXAMINER	
MOORE, WILLIAM W	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	09/673,254	SOLARI ET AL.	
	Examiner	Art Unit	
	William W. Moore	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10,11 and 18-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10,11 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant presents no claim amendments, cancellations or additions in the response filed November 12, 2003, to the rejection of record of claims 1-8, 10, 11, and 18-21 herein made in the communication mailed August 12, 2003, under the first paragraph of 35 U.S.C. § 112. This rejection of record is sustained for the reasons set forth below. independent claims 1, 18 and 19 require that all claimed DNA molecules, plasmids, host cells, and processes of using host cells for bioconversions providing, or fermentations producing, doxorubicin, comprise, contain, or utilize a specific nucleic acid restriction fragment described at, e.g., lines 4 and 5 of the amended claim 1. This 2.3 kilobase *Xba*I-*Hin*dII restriction endonuclease digest fragment was prepared, see Figure 2a, page 3, lines 16-22, page 6, lines 2-5, page 8, lines 12-14, and page 12, lines 5-11, for insertion in Applicant's claimed plasmids pIS284 and pIS287, from a prior art plasmid, pWHM603, disclosed by Guilfoile and Hutchinson, 1991, made of record herewith. The intermediate plasmid that Applicant chose to use, pBluescriptII SK+, and its multiple cloning site [mcs] permitting extraction of an inserted nucleic acid segment by restriction with endonucleases different from the endonuclease(s) used for inserting a segment in the mcs, was designed for these manipulations and commercially available, as well as widely used for such manipulations, at the time the invention was made.

Because the record does not disclose that Applicant's plasmids pIS284 or pIS287, which both comprise the 2.3 kilobase *Xba*I-*Hind*II restriction endonuclease fragment of claims 1, 18, and 19, will be made freely available to the public during the term of any patent issuing on the instant application, or that the or the prior art plasmid pWHM603 will be made freely available to the public during the term of any patent issuing on the instant application, and because the amended claims 7 and 20 describe the invention

that is either of the plasmids pIS284 or pIS287, or the use of either, a new ground of rejection and requirement for deposit of biological materials is made herein. Because the originally filed claim 13 had also described the invention that is either of the plasmids pIS284 or pIS287 and the requirement for the deposit of biological materials and accompanying rejection could have been made in either of Papers Nos. 11 or 14 mailed, respectively, June 27, 2002, and March 7, 2003, this communication is not made final.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10, 11, and 18-21 are rejected under 35 U.S.C. § 112, first paragraph, for reasons of record because the description of the specification is not enabling for the DNA region comprising both the *Streptomyces peucetius drr*A and *drr*B genes within a 2.3kb *Xba*I-*Hin*dII restriction endonuclease fragment, therefore is not enabling for plasmids pIS284 or pIS287 which comprise this DNA region. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, make and use the invention commensurate in scope with these claims.

Applicant's arguments filed November 12, 2003, have been fully considered but they are not persuasive. Applicant suggests that "starting materials described in the prior art . . . like prior art plasmid pVHM603" together with the disclosure of the specification will enable the preparation of both plasmids pIS284 or pIS287 required for practice of an invention claimed herein. It is agreed that Applicant's latter proposition is correct: If the artisan could have access to the 2.3 kilobase *Xba*I-*Hin*dII restriction endonuclease digest fragment prepared, see Figure 2a, page 3, lines 16-22, page 6, lines 2-5, page 8, lines 12-14, and page 12, lines 5-11, for insertion in Applicant's claimed plasmids pIS284 and pIS287, the specification would then enable the subject

matter of the independent claims 1, 18, 19, and 20 which require that all claimed DNA molecules, plasmids, host cells, and processes of using host cells for bioconversions providing, or fermentations producing, doxorubicin, comprise, contain, or utilize this specific nucleic acid restriction fragment described at lines 4 and 5 of the amended claim 1. Indeed, an intermediate plasmid that Applicant used, pBluescriptII SK+, and its multiple cloning site [mcs] permitting extraction of an inserted nucleic acid segment by restriction with endonucleases different from the endonuclease(s) used for inserting a segment in the mcs, was designed for the manipulations disclosed in the specification, was commercially available at the time the invention was made, and remains commercially available. Neither Applicant's argument, the specification itself, or any other aspect of the record herein shows, however, that the prior art plasmid, pWHM603, that Guilfoile and Hutchinson disclosed in 1991, or its substantial equivalent, is currently available to the artisan or will be available to the artisan for the duration of the patent term or for a period of twenty years. Because the specification does not disclose and enable, e.g., as a DNA sequence in the sequence disclosure, the nucleic acid sequence of the DNA region comprising both of the *S. peucetius drr*A and *drr*B genes within a 2.3kb *Xba*I-*Hin*dII restriction endonuclease fragment it cannot be considered to fully disclose and enable either plasmid. Claims 2-6, 8, 10, 11 and 21 are subject to this rejection in view of their dependency from claim 1.

Neither does the specification disclose that the claimed biological materials are freely available to the public, either currently or upon the issuance of a patent wherein the claimed biological materials are essential to the subject matter. The present record provides no indication, e.g., of a deposit receipt of an issuing depository indicating that the fee for maintenance of the deposits of biological material described by claims 1, 7 and 18-20 for 20-30 years has been charged to and paid by the assignee. If such a

deposit has been made, or will be made, it is noted that deposits under the terms of the Budapest Treaty are, in themselves, insufficient to satisfy 37 CFR §§1.805-1.807 unless they are disclosed on the record to be freely available to the public should a U.S. patent issue on the instant application. See, *Ex parte Hildebrand*, 15 USPQ2d 1662, 1664 (1990) (restrictions must "be irrevocably removed upon the issuance of [a] patent" because a residual requirement of secrecy resides in Rule 9.2 of the Budapest Treaty). See also, MPEP §608.01(p)(C)(3). Where 37 CFR §1.801, et seq., is applied to a deposit, including a Budapest Treaty deposit, submission of a declaration or averment, either by the **assignee** or the **attorney of record** over his or her signature and registration number, that gives these two assurances provides a basis for an enabling disclosure:

1) that all restrictions on the availability to the public of the deposited material will be removed, and,
2) that the viability of the deposits will be maintained,

both for the duration of the patent term or for a period of twenty years in accordance with 37 CFR §§1.805-1.807. See, MPEP §§2405-2411.05, wherein the latter section requires an amendment to the specification that introduces specific information concerning any deposit of biological materials. Such an amendment does not constitute new matter. The rejection of record is therefore sustained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now

571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
March 26, 2004

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER